

# *National Vaccine Plan Update of HRSA Programs*

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# National Vaccine Injury Compensation Program (VICP)

- 1 Federal level “no-fault” compensation system
- 1 Simplified, streamlined approach to litigation
  - table of compensable injuries
  - rules of evidence, discovery and other legal procedures relaxed to accelerate process
- 1 Must file first with the federal system
- 1 No age restrictions on who may file
- 1 Attorneys paid regardless of outcome provided claim filed on good faith and reasonable basis
- 1 Judgments must be rejected before filing civil lawsuit



# National Childhood Vaccine Injury Act of 1986: Safety Mandates

- 1 Reporting of certain adverse events
  - Vaccine Adverse Event Reporting System (VAERS)
- 1 Record keeping
  - date of vaccine administration
  - manufacturer
  - lot number
  - name and address of administrator
- 1 Development of vaccine information materials
  - Vaccine Information Statements (VIS's)
- 1 Institute of Medicine reviews of vaccines & adverse events
  - 1991 & 1994 reports



# VICP Setup

- 1 Program divided into 2 parts
  - “Pre-88” (vaccines administered < 10-1-88)
    - 1 Filing deadline of 2 years-4 months
    - 1 Caps on lost wages, pain and suffering, attorneys fees
    - 1 Awards from general treasury revenues
  - “Post-88” (vaccines administered on or after 10-1-88)
    - 1 Statutory deadlines: 3 years injury/2 years death (4 years in event of injury leading to a death)
    - 1 \$250K cap on pain and suffering; none for lost wages/att. fees
    - 1 Awards from vaccine excise tax



# Administrative Entities

- 1 Department of Health and Human Services
  - administers program (claims review/payments)
- 1 Department of Justice
  - represents HHS in proceedings
- 1 US. Court of Federal Claims
  - final decision maker
    - 1 entitlement *and* damages



# Advisory Commission on Childhood Vaccines (ACCV)

- 1 Reflects key stakeholders that led to NCVIA passage
- 1 9 members divided into thirds
  - physicians (at least 2 pediatricians)
  - attorneys (1 petitioner, 1 industry, 1 general)
  - public (2 parents of injured children, 1 general)
- 1 Advises Secretary on VICP operation
  - review proposed changes to the Table
  - review Vaccine Information Statements (new and modified)



# Process

- 1 Claims (“petitions”) filed by an attorney or pro se
- 1 Supporting documents:
  - medical records
  - affidavits of the parents/family (others)
  - expert witness report if necessary
- 1 HHS (VICP) staff reviews records/affidavits
- 1 Recommendation +/- entitlement sent to court by DOJ
  - for entitlement usually leads to compensation
  - against entitlement may result in a hearing
- 1 Decision-making authority in special masters



# VICP Process Highlights

- 1 Pre-88 filing deadline: 4,250 claims received
- 1 OBRA of 1993
  - permanently reauthorized VICP
  - rulemaking mechanism for adding new vaccines
- 1 Rulemaking in 1995 modifying Table (and Aids)
- 1 Rulemaking in 1997 modifying Table (and Aids)
  - excise tax changed from risk-based to flat rate
- 1 1999 deadline for filing retroactive hepatitis B claims (>350)
- 1 2007 deadline for filing retroactive influenza claims (<200)



# NVP Goal 2

## ENSURE OPTIMAL SAFETY AND EFFECTIVENESS OF VACCINES AND IMMUNIZATION

1 **Strategy 2.4.1-- Ensure viability of the National Vaccine Injury Compensation Program (VICP) through adequate funding to process claims promptly**

1 **Outcome**

- Budget shortfall in 1992 led to temporary cessation of compensation for pre-88 claims
- Increased appropriations since that time has met administrative and compensation needs of the VICP



# NVP Goal 2

## ENSURE OPTIMAL SAFETY AND EFFECTIVENESS OF VACCINES AND IMMUNIZATION

- 1 **Strategy 2.4.2-- Ensure the Vaccine Injury Table is updated periodically to reflect the latest scientific knowledge (as a basis for compensation)**
- 1 **Outcome**
  - Table modifications in 1995 & 1997 based on Congressionally-mandated reviews by the IOM
  - Table modifications in 2002 based on CDC-sponsored studies of rotavirus and intussusception
  - 2005 ACCV review of potential Table modifications for varicella, influenza, and hepatitis A vaccines
  - 2006 ACCV approval of a set of guiding principles for adding new injuries to the Table
  - 2006 ACCV recommendation that the Secretary appoint a panel of medical and scientific experts to review vaccines and conditions on the Table.



# NVP Goal 2

## ENSURE OPTIMAL SAFETY AND EFFECTIVENESS OF VACCINES AND IMMUNIZATION

- 1 **Strategy 2.4.3-- Ensure that new vaccines recommended for universal immunization are covered under the VICP**
- 1 Outcome: Process improvements
  - 1997: general category added to the Table (last box) for any new vaccine recommended by CDC for “routine administration to children,”
  - 1997: “Taxpayer Relief Act of 1997 placed a flat tax rate of 75 cents per dose (disease prevented) for all VICP-covered vaccines
- 1 Outcome: Adding new vaccines (original 7 vaccines increased to 16)
  - 1997: Hib, hepatitis B, varicella
  - 1998: rotavirus
  - 2001: pneumococcal conjugate
  - 2004: hepatitis A
  - 2005: trivalent influenza
  - 2007: meningococcal and human papillomavirus



# NVP Goal 3

## BETTER EDUCATE....ON THE BENEFITS AND RISKS OF IMMUNIZATIONS

1 **Strategy 3.4.2**-- Assess and improve health provider knowledge and patient awareness of the VICP

1 Outcome

- Booklet and brochure in English and Spanish
- Website ([www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation))
- Exhibiting at medical and legal conferences
- Press releases when new vaccines/ injuries added
- Proactively seeking speaking engagements at medical conferences
- Networking with national organizations (e.g., AARP)



# National Vaccine Plan

## Additional HRSA Program Roles

**Goal 3. Better educate the public and members of the health professions on the benefits and risks of immunization**

Objective 3.1 Increase public demand for immunization, especially among populations at risk of underimmunization

Objective 3.2 Improve the immunization practices of all health care providers

Objective 3.3 Increase the awareness of the benefits of immunization among special target audiences (third-party payers, employers, legislators, community leaders, hospital administrators, etc.)

Objective 3.4 Develop more effective methods of communicating the benefits and risks of immunization to health care providers, patients and parents/guardians



# National Vaccine Plan

## Additional HRSA Program Roles (con't.)

**Goal 4. Achieve better use of existing vaccines to prevent disease, disability, and death**

Objective 4.2 Increase immunization coverage levels for infants and children

Objective 4.3 Maintain immunization coverage levels for school-aged children

Objective 4.4 Increase immunization coverage levels among older adolescents, adults, and the elderly



# HRSA Programs Impacting Vaccination Rates

## 1 Bureau of Primary Health Care

1200 Health Centers at 13,000 sites serve 15 million persons via low cost vaccines purchased through the Prime Vending Program, Vaccines for Children, Medicaid

## 1 Maternal Child Health Bureau

Serving approximately 35 million women, infants, children and teenagers via Title V and EPSDT via the states, with some having additional emphasis on improving vaccination rates

## 1 HIV AIDS Bureau

Serve almost 1 million clients providing direct funding for primary care, ADAP and the AETC (AIDS Education and Training Centers)

## 1 Rural Health

Demonstration project for improving access to care in rural communities and policy initiatives



# Center for Quality HRSA Wide Immunization Measures

- 1 **Children:** Number of children in the “universe” who received all of the following: 4 DTP/DTaP, 3 IPV, 1 MMR, 3 Hib, 3 HepB, 1 VZV (Varicella) and 4 Pneumococcal conjugate, prior to or on their 2nd birthday
- 1 **Adults/Seniors:** Percentage of patients  $\geq 50$  years of age who have received influenza vaccine (Stratification 50-64 years and  $>65$  years)
- 1 **Seniors:** Percentage of patients  $\geq 65$  years of age who have ever received pneumococcal vaccine



## Goal 3 Public Vaccine Education

- 1 HRSA grantees are required to provide services which are concordant with the diverse culture, language and literacy of the patients they serve
- 1 28% BPHC grantee patients are better served in languages other than English
- 1 Our grantees to provide outreach in a myriad of settings i.e. schools, religious institutions, nursing homes, jails etc. to educate individuals, local and state decision makers about the risks and benefits of immunizations
- 1 Many of our health centers increase awareness and public demand via local media campaigns on the radio, television and print media
- 1 Most centers use CDC and local health department vaccine materials, which they may need to translate and interpret for different dialects and languages



# Goal 3 Clinician Education

- 1 HRSA clinicians are provided vaccine education via information from the CDC, local health departments etc.
- 1 HRSA clinicians in a wide range of CME educational programs including vaccinations
- 1 HRSA grantees reimburse clinicians and others for CME
- 1 Area Health Education Centers provide continuing education for all levels of providers



# Goal 4 Immunization Coverage for All Age Cohorts

- 1 HRSA sites provide immunizations and have high immunization rates for infants and young children who are usually covered by Medicaid, CHIP and Vaccine for Children Programs. (99% of BPHC sites provide immunizations)
- 1 Immunization rates decrease with adolescents who may not be as adequately covered or mobile ( especially for hepatitis b and gardisil)
- 1 Immunization rates especially for Pneumococcal and Influenza vaccine are more problematic for our adults and seniors (who make up about 7% of our population)
- 1 HRSA sites attempt to overcome the lower rates by outreaching to schools and the community for older adults and seniors



# Maternal and Child Health Bureau

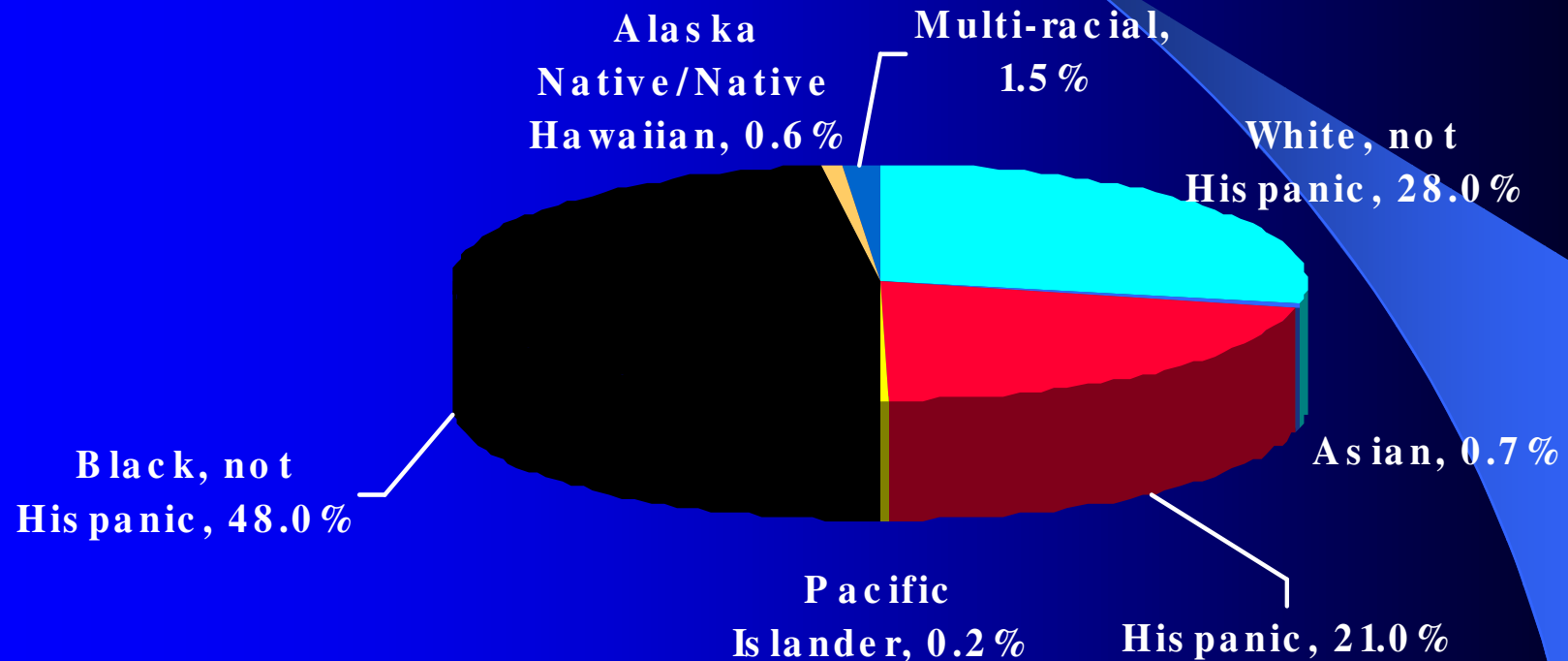
## Total Title V Program Recipients

- 1 Pregnant Women 2,599,338
- 1 Infants Less Than 1 Year 3,949,593
- 1 Children 1-22 Years 23,626,463
- 1 CSHCN 1,418,445
- 1 Others 3,046,093
- 1 Total 34,639,932



# HIV/AIDS Bureau

Race of Duplicate Clients Served by CARE Act Providers, 2005  
N=952, 563 duplicated clients



Source: Ryan White HIV/AIDS Program Data Report, 2005

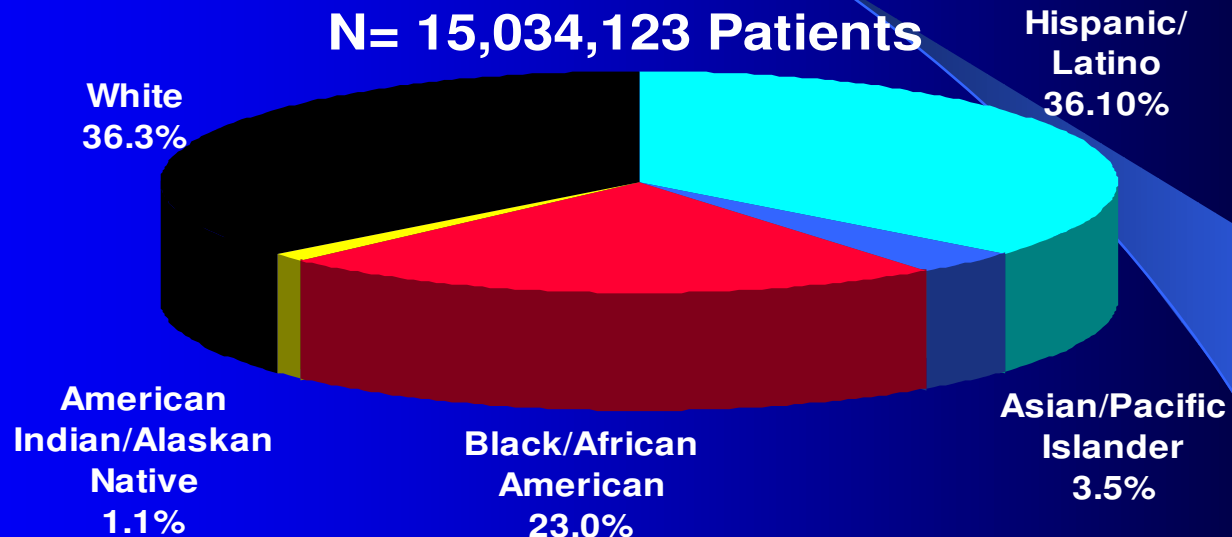
Race/ethnicity was unknown or not reported for 36, 431 clients



# Bureau of Primary Health Care

## Health Center Patients by Race and Ethnicity

N= 15,034,123 Patients



**28.9% of patients are best served in a language other than English**

Source: Uniform Data System, 2006

